NOV 2 2 2002

K021397

510(k) Summary
for
Embosphere® Microspheres ~~and EmboGold™ M~~icrospheres for use in Uterine Fibroid Embolization

1. SPONSOR

Biosphere Medial, Inc.
1050 Hingham Street
Rockland, MA 02370

Contact Person: Jon McGrath, Vice President of Research
Telephone: 781-681-7950

Date Prepared: April 30, 2002

2. DEVICE NAME

Proprietary Name: Embosphere® Microspheres and EmboGold™ Microspheres for use in Uterine Fibroid Embolization

Common/Usual Name: Artificial emboli

Classification Name: Artificial Embolization Device (21 CFR 882.5950 and 21 CFR 870.3300)

3. PREDICATE DEVICES

Embosphere® Microspheres as reviewed under K991549 and EmboGold™ Microspheres as reviewed under K010026.

4. INTENDED USE

Embosphere® and EmboGold™ Microspheres are intended for embolization of arteriovenous malformations and hypervascular tumors, including and uterine fibroids.

5. DEVICE DESCRIPTION

Embosphere® and EmboGold™ Microspheres are small, flexible, hydrophilic, biocompatible spheres made of acrylic polymer and porcine-derived gelatin. The microspheres are packaged in 0.9% saline and are provided sterile and nonpyrogenic. They are delivered to the target site by a catheter under fluoroscopic control.

Both products are provided in six size ranges in order to allow physicians to choose the calibration necessary for the vessel being embolized. The size ranges available are:

40-120 microns
100-300 microns
300-500 microns
500-700 microns
700-900 microns
900-1200 microns

Only microspheres of 500 microns or greater should be used for the embolization of uterine fibroids.

The only difference between Embosphere® and EmboGold™ Microspheres is the colorization of the EmboGold™ Microspheres. Embosphere® Microspheres are translucent, although they are visible to the naked eye when in suspension. EmboGold™ Microspheres are purple/red in color for improved visibility during preparation and handling by the physician.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

Embosphere® and EmboGold™ Microspheres for uterine fibroid embolization are substantially equivalent to the same products when indicated for the more general intended use of embolization of hypervascular tumors. Clinical data was collected in a prospective clinical study to support the safety and effectiveness of Embosphere® Microspheres for uterine fibroid embolization. EmboGold™ Microspheres are the same product as Embosphere® Microspheres, except for the colorization. Data to support the substantial equivalence of EmboGold™ Microspheres to Embosphere® Microspheres was previously provided in K010026.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2002

BioSphere Medical, Inc.
% Sheila Hemeon-Heyer, J.D., R.A.C.
Senior Staff Consultant
Medical Device Consultants
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K021397
Trade/Device Name: Embosphere® Microspheres for UFE
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial Embolization device
Regulatory Class: III
Product Code: 85 NAJ
Dated: August 27, 2002
Received: August 28, 2002

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021397

Device Name: Embosphere® Microspheres for use in Uterine Fibroid Embolization

Indications for Use:

Embosphere Microspheres are indicated for use in embolization of arteriovenous malformations, hypervascular tumors, and symptomatic uterine fibroids.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021397

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96